

REMARKS

After entry of this Amendment, the pending claims are: claims 16-18, 25-27 and 32. The Non Final Office Action dated October 10, 2008 has been carefully considered. Claims 19-24 and 28-31 have been canceled, without prejudice. Claims 1-15 were previously canceled without prejudice. Per the Examiner Interview held on October 28, 2008 between Supervisory Patent Examiner Robert, Examiner Merene and the Undersigned, claims 16-18 and 25-27 have been amended such that they are directed to a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae. Claims 16, 25 and 32 have been amended to include structural elements of the claimed device in the preamble of the claims and method elements into the body of the claims. Accordingly, no new matter has been added as the present amendment generally includes subject matter that was previously included in the amended claims and support for additional elements can be found throughout the specification and drawings. Reconsideration and allowance of the pending claims in view of the above Amendments and the following remarks is respectfully requested.

In the Non Final Office Action dated October 10, 2008, the Examiner:

- rejected claims 16-31 under 35 U.S.C. 101 for being drawn to non-statutory subject matter;
- rejected claims 16, 17, 23-26 and 32 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,776,198 to Rabbe *et al.* ("Rabbe") in view of U.S. Patent No. 6,015,436 to Schonhoffer ("Schonhoffer");

- rejected claims 18-20, 22, 27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Schonhoffer in further view of U.S. Patent No. 6,899,734 to Castro *et al.* ("Castro"); and
- rejected claims 21 and 30 under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Schonhoffer in further view of Castro and in further view of U.S. Patent No. 6,106,539 to Fortier ("Fortier").

35 U.S.C. 101 REJECTION

Claims 16-31 were rejected under 35 U.S.C. 101 for being drawn to non-statutory subject matter. Specifically claims 16-31 were rejected for positively reciting a part of the human body. With respect to claims 19-24 and 28-31, which have been canceled, this rejection is believed to be moot. With respect to claims 16-18 and 25-27, Applicants respectfully submit that these claims have been amended so that they are now directed to a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae. As such, it is believed that this rejection has been overcome. Withdrawal of this rejection is respectfully requested.

INDEPENDENT CLAIM 16

Independent claim 16 and dependent claims 17, 23 and 24, which are dependent on claim 16, have been rejected as being unpatentable over Rabbe in view of Schonhoffer. Dependent claims 18-20 and 22 have been rejected as being unpatentable over Rabbe in view of Schonhoffer in further view of

Castro. Dependent claim 21 has been rejected as being unpatentable over Rabbe in view of Schonhoffer in view of Castro in further view of Fortier. With respect to claims 19-24, which have been canceled, these rejections are believed to be moot. Applicants respectfully traverse these rejections with respect to the above-listed remaining claims.

Referring to Figs. 3 and 7-9, Rabbe discloses an adjustable height vertebral body replacement assembly 20 including a cylindrical body 21 with external threads 32, threaded endplates 22 and end caps 23. Set screws 24 are provided to selectively fix each endplate 22 to the threaded cylindrical body 21. The external threads 32 are configured to engage the threaded endplates 22 and each endplate 22 includes a bore 40 with internal threads 41 that mate with the external threads 32. The external threads 32 are cut in opposite directions so that the endplates 23 can be drawn together or apart by rotating only the threaded cylindrical body 21. Thus, as the threaded cylindrical body 21 is rotated in one direction, the threads 32 at each of the ends engage the internal threads 41 formed on the endplates 22 to move the endplates 22 closer or farther apart so that the user can adjust the overall height of the implant. The endplates 22 include spikes 91, 120 to penetrate the end plate of the adjacent vertebra to secure the position of the implant in situ and the spikes 91, 120 are constantly positioned on an opposite side of the endplates 22 from the cylindrical body 21. The end caps 23 span the bores 40 in the endplates 22 such that terminal ends of the cylindrical body 21 do not extend beyond an outer face of the endplates 22 or the end caps 23 and do not contact end plates of the vertebrae in an implanted position.

In use, after the damaged vertebra is removed, the optimum vertebral height is determined and the threaded cylindrical body 21 and threaded endplates 22 are fitted together to achieve the proper

height. Once the endplates 22 and threaded cylindrical body 21 have been adjusted to the correct height between the vertebrae, the set screws 24 are threaded into the threaded openings 39 formed in the endplates 22 so that the set screws 24 can engage and secure the threaded cylindrical body 21 with respect to the endplates 22. Thus, the set screws 24 provide a means for fixing the components together and for preventing rotation of the cylindrical body 21 with respect to either of the endplates 22.

Referring to Figs. 1, 2 and 4, Schonhoffer discloses an adjustable height intervertebral implant consisting of an upper and a lower end implant parts 1, 2 and a center implant part 3 located between them. The center implant part 3 is threadably connected via a thread 4 with the upper end implant part 1 so that rotation of the center implant part 3 adjusts the height of the implant by moving the upper and lower parts 1, 2 relative to each other.

Independent claim 16 of the present application is directed to a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae, the intervertebral implant comprising an intervertebral spacer body having an upper endface to contact at least a portion of the upper vertebra and at least one end member including a plurality of spikes for engaging at least a portion of the upper vertebra, and the method recites, as follows:

a) providing access to the intervertebral disc space; b) inserting the intervertebral implant into the intervertebral disc space such that the upper endface of the spacer body contacts at least a portion of the upper vertebra; and c) slidably, non-rotatably moving the at least one end member with respect to the intervertebral spacer body from a second position wherein the plurality of spikes do not extend beyond the upper endface to a first position wherein the plurality of spikes extend beyond the upper endface to extend at least partially into engagement with the upper vertebra. (Emphasis added).

It is respectfully submitted that there is no disclosure, teaching or suggestion in Rabbe and/or Schonhoffer, either alone or in combination, of a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae wherein the intervertebral implant includes an intervertebral spacer body having an upper endface to contact at least a portion of the upper vertebra and at least one end member including a plurality of spikes for engaging at least a portion of the upper vertebra. The intervertebral implant being inserted into the intervertebral disc space such that the upper endface of the spacer body contacts at least a portion of the upper vertebra and the end member is then slidably, non-rotatably moved with respect to the spacer body from a second position wherein the plurality of spikes do not extend beyond the upper endface to a first position wherein the plurality of spikes extend beyond the upper endface to extend at least partially into engagement with the upper vertebra.

Rather, at best, Rabbe discloses an adjustable height intervertebral implant comprising a threaded cylindrical body 21 and a threaded endplate 22 wherein the threaded endplate 22 contacts the adjacent vertebra. There is no disclosure in Rabbe of the threaded cylindrical body 21 contacting the adjacent vertebra. In fact, such interpretation would be against the explicit teaching of Rabbe which is to provide an adjustable height implant with circular end faces 23 that cover the end faces of the cylindrical body 21, thereby preventing the body 21 from contacting the vertebral end plates. That is, it would be against the explicit teachings of Rabbe to provide a cylindrical body 21 that contacts the adjacent vertebrae as this would eliminate the adjustable height feature disclosed in Rabbe.

Similarly, Schonhoffer discloses an adjustable height intervertebral implant consisting of an upper and a lower end implant parts 1, 2 and a center implant part 3 located between them. The center implant part 3 is threadably connected via a thread 4 with the upper end implant part 1 so that rotation of the center implant part 3 adjusts the overall height of the implant. There is no disclosure in Schonhoffer of the center implant part 3 contacting the adjacent vertebra. In fact, such interpretation would be against the explicit teaching of Schonhoffer which is to provide an adjustable height implant.

Both Rabbe and Schonhoffer disclose adjustable height intervertebral implants wherein an end member is moved with respect to a central member so that the overall height of the implant is adjustable. That is, both Rabbe and Schonhoffer disclose end members that contact the adjacent vertebrae, the end members being rotatably moveable with respect to the central member so that the overall height of the implant can be adjusted to accommodate the height of the intervertebral disc space. The central member in both Rabbe and Schonhoffer does not contact the adjacent vertebrae and is not slidably, non-rotatably movable relative to the end members. This is in distinction to the implant recited in independent claim 1 which requires, inter alia, an intervertebral spacer body having an upper endface and at least one end member wherein the implant is inserted into the intervertebral disc space such that the upper endface of the spacer body contacts at least a portion of the upper vertebra and the end member is then slidably, non-rotatably moved with respect to the intervertebral spacer body from a second position wherein the plurality of spikes do not extend beyond the upper endface to a first position wherein the plurality of spikes extend beyond the upper endface to extend at least partially into engagement with the upper vertebra.

As such, Applicants respectfully submit that neither Rabbe nor Schonhoffer, either alone or in combination, disclose, teach, or suggest all of the limitations of independent claim 16. Thus, it is respectfully submitted that independent claim 16 is allowable over Rabbe and/or Schonhoffer, either alone or in combination. Allowance of independent claim 16 is respectfully requested.

Furthermore, as claims 17 and 18 all depend from independent claim 16, it is submitted that these claims are equally allowable for at least this reason. Withdrawal of these rejections and allowance of claims 17 and 18 is also respectfully requested.

With respect to claim 18 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Schonhoffer in further view of Castro, it is respectfully submitted that Castro does not overcome the short comings of Rabbe and/or Schonhoffer. Castro was cited for the proposition that it would be obvious for one of ordinary skill in the art to incorporate one or more elastically deformable projections extending from an inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured. Without addressing the merits of this argument, it is respectfully submitted that, for at least the above-identified reason, neither Rabbe, Schonhoffer nor Castro, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 16 and, therefore, dependent claim 18. Thus, it is respectfully submitted that dependent claim 18 is allowable over Rabbe, Schonhoffer and/or Castro. Withdrawal of this rejection and allowance of dependent claim 18 is respectfully requested.

INDEPENDENT CLAIM 25

Independent claim 25 and claim 26, which is dependent on claim 25, have been rejected as being unpatentable over Rabbe in view of Schonhoffer. Dependent claims 27-29 and 31 have been rejected as being unpatentable over Rabbe in view of Schonhoffer in further view of Castro. Dependent claim 30 has been rejected as being unpatentable over Rabbe in view of Schonhoffer in view of Castro in further view of Fortier. With respect to claims 28-31, which have been canceled, these rejections are believed to be moot. Applicants respectfully traverse these rejections with respect to the above-listed remaining claims.

Independent claim 25 is directed to a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae, the intervertebral implant including an intervertebral spacer body having an upper endface to contact at least a portion of the upper vertebra and a lower endface to contact at least a portion of the lower vertebra; a first end member including a plurality of spikes for engaging at least a portion of the upper vertebra; and a second end member including a plurality of spikes for engaging at least a portion of the lower vertebra and the method recites, as follows:

a) providing access to the intervertebral disc space; b) **inserting the intervertebral implant into the intervertebral disc space such that the upper endface of the spacer body contacts at least a portion of the upper vertebra and the lower endface of the spacer body contacts at least a portion of the lower vertebra; and c) slidably, non-rotatably moving the first and second end members with respect to the intervertebral spacer body between a second position wherein the plurality of spikes formed on the first and second end members do not extend beyond the upper and lower endfaces and a first position wherein the plurality of spikes formed on the**

first and second end members extend beyond the upper and lower endfaces and at least partially into engagement with the upper and lower vertebrae, respectively.
(Emphasis added).

For reasons similar to those listed above, it is respectfully submitted that neither Rabbe and/or Schonhoffer, either alone or in combination, discloses, teaches, or suggests a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae wherein the intervertebral implant includes an intervertebral spacer body having an upper endface to contact at least a portion of the upper vertebra, a lower endface to contact at least a portion of the lower vertebra, a first end member including a plurality of spikes for engaging at least a portion of the upper vertebra and a second end member including a plurality of spikes for engaging at least a portion of the lower vertebra. The intervertebral implant is inserted into the intervertebral disc space such that the upper endface of the spacer body contacts at least a portion of the upper vertebra, the lower endface of the spacer body contacts at least a portion of the lower vertebra and the first and second end members are slidably, non-rotatably moved with respect to the intervertebral spacer body between a second position wherein the plurality of spikes formed on the first and second end members do not extend beyond the upper and lower endfaces and a first position wherein the plurality of spikes formed on the first and second end members extend beyond the upper and lower endfaces and at least partially into engagement with the upper and lower vertebrae, respectively.

Both Rabbe and Schonhoffer disclose adjustable height intervertebral implants wherein an end member is moved with respect to a central member so that the overall height of the implant is adjustable. That is, both Rabbe and Schonhoffer disclose end members that contact the adjacent

vertebrae, the end members being rotatably moveable with respect to the central member so that the overall height of the implant can be adjusted to accommodate the height of the intervertebral disc space. The central member in both Rabbe and Schonhoffer does not contact the adjacent vertebrae and is not slidably, non-rotatably movable relative to the end members. This is in distinction to the implant recited in independent claim 25 which requires, inter alia, an intervertebral spacer body having an upper endface to contact at least a portion of the upper vertebra, a lower endface to contact at least a portion of the lower vertebra, a first end member including a plurality of spikes for engaging at least a portion of the upper vertebra and a second end member including a plurality of spikes for engaging at least a portion of the lower vertebra wherein the implant is inserted into the intervertebral disc space such that the upper endface of the spacer body contacts at least a portion of the upper vertebra, the lower endface of the spacer body contacts at least a portion of the lower vertebra and the first and second end members are then slidably, non-rotatably moved with respect to the intervertebral spacer body between a second position wherein the plurality of spikes formed on the first and second end members do not extend beyond the upper and lower endfaces and a first position wherein the plurality of spikes formed on the first and second end members extend beyond the upper and lower endfaces and at least partially into engagement with the upper and lower vertebrae, respectively.

Thus, Applicants respectfully submit that neither Rabbe nor Schonhoffer, either alone or in combination, disclose, teach, or suggest all of the limitations of independent claim 25. Therefore, it is respectfully submitted that independent claim 25 is allowable over Rabbe and/or Schonhoffer, either alone or in combination. Allowance of independent claim 25 is respectfully requested.

Furthermore, as claims 26 and 27 all depend from independent claim 25, it is submitted that these claims are equally allowable for at least this reason. Withdrawal of these rejections and allowance of claims 26 and 27 is also respectfully requested.

With respect to claim 27 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe in view of Schonhoffer in further view of Castro, it is respectfully submitted that Castro does not overcome the short comings of Rabbe and/or Schonhoffer. Castro was cited for the proposition that it would be obvious for one of ordinary skill in the art to incorporate one or more elastically deformable projections for engaging the intervertebral spacer body when the first and second end members are in the first position so that the position of the first and second end members with respect to the spacer body are secured. Without addressing the merits of this argument, it is respectfully submitted that, for at least the above-identified reason, neither Rabbe, Schonhoffer nor Castro, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 25 and, therefore, dependent claim 27. Thus, it is respectfully submitted that dependent claim 27 is allowable over Rabbe, Schonhoffer and/or Castro. Withdrawal of this rejection and allowance of dependent claim 27 is respectfully requested.

INDEPENDENT CLAIM 32

Independent claim 32 has been rejected as being unpatentable over Rabbe in view of Schonhoffer. Applicants respectfully traverse this rejection with respect to independent claim 32.

Independent claim 32 is directed to a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae, the intervertebral implant having an

intervertebral spacer body having an upper endface and a lower endface for contacting the upper and lower vertebrae, respectively; and first and second end members, the first and second end members including a plurality of spikes formed on a surface thereof, the method recites as follows:

a) inserting the intervertebral implant into the intervertebral disc space so that the upper endface formed on the intervertebral spacer body contacts the upper vertebra and the lower endface formed on the intervertebral spacer body contacts the lower vertebra; b) non-rotatably, slidably moving the first and second end members with respect to the intervertebral spacer body so that the plurality of spikes engage the upper and lower vertebrae, respectively; and c) securing the first and second end members with respect to the intervertebral spacer body. (Emphasis Added).

For reasons similar to those listed above, it is respectfully submitted that neither Rabbe and/or Schonhoffer, either alone or in combination, discloses, teaches, or suggests a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae wherein the intervertebral implant has an intervertebral spacer body having an upper endface and a lower endface for contacting the upper and lower vertebrae, respectively, and first and second end members, wherein the first and second end members are non-rotatably, slidably disposed on the intervertebral spacer body. The intervertebral implant is inserted into the intervertebral disc space so that the upper endface formed on the intervertebral spacer body contacts the upper vertebra and the lower endface formed on the intervertebral spacer body contacts the lower vertebra. The first and second end members are then non-rotatably, slidably moved with respect to the intervertebral spacer body so that the plurality of spikes engage the upper and lower vertebrae, respectively.

Both Rabbe and Schonhoffer disclose adjustable height intervertebral implants wherein an end member is moved with respect to a central member so that the overall height of the implant is adjustable. That is, both Rabbe and Schonhoffer disclose end members that contact the adjacent vertebrae, the end members being rotatably moveable with respect to the central member so that the overall height of the implant can be adjusted to accommodate the height of the intervertebral disc space. The central member in both Rabbe and Schonhoffer does not contact the adjacent vertebrae and is not slidably, non-rotatably movable relative to the end members. This is in distinction to the implant recited in independent claim 32 which requires, inter alia, an intervertebral spacer body having an upper endface and a lower endface for contacting the upper and lower vertebrae, respectively; and first and second end members, the first and second end members including a plurality of spikes formed on a surface thereof wherein the implant is inserted into the intervertebral disc space so that the upper endface formed on the intervertebral spacer body contacts the upper vertebra and the lower endface formed on the intervertebral spacer body contacts the lower vertebra; and the first and second end members are then non-rotatably, slidably moved with respect to the intervertebral spacer body so that the plurality of spikes engage the upper and lower vertebrae, respectively.

Applicants respectfully submit that neither Rabbe nor Schonhoffer, either alone or in combination, disclose, teach, or suggest all of the limitations of independent claim 32. Therefore, it is respectfully submitted that independent claim 32 is allowable over Rabbe and/or Schonhoffer, either alone or in combination. Allowance of independent claim 32 is respectfully requested.

CONCLUSION

Based upon the above-listed amendments and remarks, Applicants respectfully submit that the present application, including claims 16-18, 25-27 and 32, is in condition for allowance and such action is respectfully requested.

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicant's attorney at the number listed below.

Date: January 6, 2009

Respectfully submitted,

/Giuseppe Molaro/
Giuseppe Molaro
Registration No. 52,039

For: Brian M. Rothery
Registration No. 35,340

Attorney for Applicants
Stroock & Stroock & Lavan LLP
180 Maiden Lane
New York, New York 10038
(212) 806-6114